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Historical Perspectives Reduced Incidence of Menstrual Toxic-Shock Syndrome -- United States, 1980-1990

In May 1980, investigators reported to CDC 55 cases of toxic-shock syndrome (TSS) (1), a newly recognized illness characterized by high fever, sunburn-like rash, desquamation, hypotension, and abnormalities in multiple organ systems (2). Fifty-two (95%) of the reported cases occurred in women; onset of illness occurred during menstruation in 38 (95%) of the 40 women from whom menstrual history was obtained. National and state-based studies were initiated to determine risk factors for this disease. In addition, CDC established national surveillance to assess the magnitude of illness and follow trends in disease occurrence; 3295 definite cases have been reported since surveillance was established (Figure 1).

In June 1980, a follow-up report described three studies which detected an association between TSS and the use of tampons (3). Case-control studies in Wisconsin and Utah and a national study by CDC indicated that women with TSS were more likely to have used tampons than were controls. The CDC study also found that continuous use of tampons was associated with a higher risk of TSS than was alternating use of tampons and other menstrual products. Subsequent studies established that risk of TSS was substantially greater in women who used RelyPr* brand tampons than in users of other brands and that risk increased with increased tampon absorbency (4-6). In September 1980, RelyPr tampons were voluntarily withdrawn from the market by the manufacturer.

In 1980, 890 cases of TSS were reported, 812 (91%) of which were associated with menstruation. In 1989, 61 cases of TSS were reported, 45 (74%) of which were menstrual. In 1980, 38 (5%) of 772 women with menstrual TSS died; in 1988 and 1989, there were no deaths among women with menstrual TSS. Reported by: Meningitis and Special Pathogens Br, Div of Bacterial Diseases, Center for Infectious Diseases, CDC.

Editorial Note

Editorial Note: The number of TSS cases reported annually to CDC has decreased substantially in the 10-year period since menstrual TSS was first recognized. Changes in public awareness and diminished attention to TSS in the medical literature might have resulted in reduced diagnosis and reporting. However, reporting of nonmenstrual TSS has remained constant during this time while menstrual TSS reporting has decreased.

A multistate active surveillance study in 1986-1987 confirmed the trends detected by national passive surveillance (7). Through active case-finding efforts in an aggregate population of 34 million persons, the rate for menstrual TSS was determined to be 1.0 per 100,000 women 15-44 years of age (7). This rate represented a substantial reduction from rates reported in similar studies in 1980 (6.2 per 100,000 women 12-49 years of age in Wisconsin (8), 9.0 per 100,000 women 12-45 years of age in Minnesota (9), and 12.3 per 100,000 women 12-49 years of age in Utah (10)). Active surveillance also confirmed that the proportion of TSS associated with menstruation had decreased considerably: in 1988, menstrual TSS accounted for 55% of cases detected both by active surveillance (7) and by the passive surveillance system.

A principle reason for the decreased incidence of menstrual TSS may be decreases in the absorbency of tampons. In 1980, when tampon absorbency (in vitro) ranged from 10.3-20.5 g (4), very high absorbency products (greater than 15.4 g) were used by 42% of tampon users (9). After the association between TSS and absorbency was recognized, manufacturers lowered the absorbency of tampons. In 1982, the Food and Drug Administration (FDA) issued a regulation requiring that tampon package labels advise women to use the lowest absorbency tampons compatible with their needs. By 1983, tampon absorbency ranged from 6.3-17.2 g (6), and the proportion of tampon users using very high absorbency tampons had declined to 18%. By 1986, very high absorbency products were used by only 1% of women who used tampons. Effective March 1990, the FDA instituted standardized absorbency labeling of tampons, which currently range from 6-15 g.

Tampon composition has also changed since 1980. RelyPr tampons consisted of polyester foam and cross-linked carboxymethylcellulose, a combination that is no longer used in tampons. Polyacrylate-containing tampons were withdrawn from the market in 1985. Current tampons are manufactured from cotton and/or rayon. The unique composition of RelyPr tampons may have been responsible for the increased risk associated with those products (11); however, the role of current tampon composition as an independent risk factor for TSS is unclear since composition may vary even for a particular brand and style of tampon marketed at a given time.

Other factors may have contributed to decreased reports of menstrual TSS. For example, public awareness of the syndrome may cause women to seek medical care earlier in their illness; milder disease may not meet the surveillance case definition of severe multisystem illness. Increased variety in menstrual products and concern related to TSS may have resulted in fewer women using tampons or fewer using tampons continuously.

Current public health efforts to prevent menstrual TSS include tampon package labels and package inserts which describe early signs and symptoms of TSS and warn the consumer about the risk associated with tampons. Tampon users are encouraged to select lower absorbency products to further decrease risk of TSS. Standardized absorbency labeling permits consumers to compare absorbency between brands.

The precise mechanism by which RelyPr tampons increased the risk of TSS is unknown. The increased

risk associated with high absorbency tampons is also poorly understood; high absorbency may be a surrogate for another effect. However, the withdrawal of RelyPr tampons and the subsequent decrease in use of high absorbency tampons correlate with a marked decrease in incidence of menstrual TSS. The rapid demonstration of the risk of RelyPr and high absorbency tampons resulted in prompt public health interventions and substantial reduction in menstrual TSS.

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